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Description**BACKGROUND OF THE INVENTION**

[0001] In the diagnosis and monitoring of diseases, medical tests are often performed on blood, tissue, or other media sampled from patients. Such tests are often performed on automated testing machines. In a typical scenario, a doctor requests that a particular test be performed, and a sample is taken from the patient. The sample is sent to an on-site or off-site testing lab, and the results of the test are returned to the doctor for review and reporting to the patient.

[0002] In order to ensure proper diagnosis and treatment, a medical testing machine should be calibrated before its first use and periodically thereafter.

BRIEF SUMMARY OF THE INVENTION

[0003] According to one aspect, provided is a method of performing a calibration in a medical testing machine comprising an extraction mechanism for aspirating and re-injecting liquids, the method comprising: automatically detecting that a package of calibration material has been inserted into the medical testing machine; performing, by the medical testing machine, a calibration sequence using the calibration material to ascertain a calibration parameter for the medical testing machine; and storing the calibration parameter in electronic storage for use in later tests performed by the medical testing machine; the method being characterized in that the package of calibration material comprises a vial in which the calibration material is provided in a lyophilized state, and the method further comprises controlling the medical testing machine to automatically reconstitute the lyophilized material before performing the calibration sequence by using the extraction mechanism to add a liquid to the vial containing the material in the lyophilized state; and wherein the method further comprises using the extraction mechanism for agitating the reconstituted material by aspirating at least some of the reconstituted material from the vial containing the reconstituted material and by re-injecting the aspirated reconstituted material into the vial. In some embodiments, the method further includes reading a calibration setpoint from the package of calibration material. In some embodiments, the medical testing machine performs liquid chromatography that uses a washing solution, and the washing solution is also used to reconstitute the lyophilized material. The medical testing machine may perform high performance liquid chromatography. The medical testing machine may perform a test that measures a level of HbA1c hemoglobin in blood. In some embodiments, the method further comprises comparing the calibration parameter with a predetermined condition, and automatically re-running the calibration if the calibration parameter does not meet the predetermined condition. In some embodiments, the method further comprises comparing the calibration parameter with a predetermined condition, and automatically re-running the calibration if the calibration parameter meets the predetermined condition. The calibration may be a two-point calibration, in which two calibration parameters are ascertained. The calibration parameters may include a slope and an intercept.

[0004] According to another aspect, provided is a medical testing machine comprising a testing system for performing a medical test on media sampled from patients; an extraction mechanism for aspirating and re-injecting liquids; a media handling mechanism; a processor; and a memory, the memory holding instructions that when executed by the processor cause the medical testing machine to: automatically recognize that a package of calibration material has been inserted into the medical testing machine, wherein the package of calibration material comprises a vial in which at least some of the calibration material is in a lyophilized state; perform a calibration sequence using the calibration material to ascertain a calibration parameter for the medical testing machine; and store the calibration parameter in the memory for use in later tests performed by the medical testing machine; the medical testing machine being characterized in that the instructions, when executed by the processor, further cause the extraction mechanism of the medical testing machine to, as part of the calibration sequence, add a liquid to the vial containing the material in the lyophilized state in order to automatically reconstitute at least some of the calibration material from the lyophilized state; and wherein the instructions, when executed by the processor, further cause the extraction mechanism of the medical testing machine to agitate the reconstituted material by aspirating at least some of the reconstituted material from the vial containing the reconstituted material and re-injecting the aspirated reconstituted material into the vial. In some embodiments, the medical testing machine further includes a STAT input, and the medical testing machine automatically recognizes that the package of calibration material has been inserted into the STAT input. The medical testing machine may perform high performance liquid chromatography. The medical testing machine may perform a test that measures a level of HbA1c hemoglobin in blood. In some embodiments, the medical testing machine further includes a display, and the instructions, when executed by the processor, further cause the medical testing machine to present a user interface screen on the display indicating the progress of the calibration sequence. The display may be a touchscreen display.

[0005] Such a general method of performing a calibration in a testing system is known from US Patent Application No. 2005/024963. The automatic reconstitution of lyophilized reagent and reference material in a vial is disclosed in US Patent No. 5,578,272. The agitation of a liquid in a vial by aspiration and re-injection is disclosed in EP-A-0527059.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006]

FIG. 1 shows a medical testing machine in accordance with example embodiments of the invention.

FIG. 2 shows a vial as may be used in the medical testing machine of FIG. 1, in more detail.

FIG. 3 shows a simplified block diagram of the architecture of the medical testing machine of FIG. 1, in accordance with embodiments of the invention.

FIG. 4A illustrates a package of calibration materials according to one embodiment.

FIG. 4B illustrates a package of calibration materials according to another embodiment.

FIG. 5 illustrates an example user interface screen.

FIG. 6 shows an example user interface screen for providing user feedback about the progress of a calibration sequence.

FIG. 7 illustrates an example user interface screen for recalling stored information relating to a calibration sequence.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention provide an improved calibration process for a medical testing machine.

One example of a condition that requires ongoing monitoring and repeated testing is diabetes. Diabetes is a name given to a class of conditions in which a patient exhibits elevated blood sugar levels, either because the patient's body does not produce enough of the metabolism-regulating hormone insulin, or because cells in the patient's body do not respond properly to insulin. Diabetes is increasingly prevalent in the United States and other parts of the world.

The management of diabetes often involves frequent blood sugar measurements, and many patients use at-home blood sugar testing devices to take frequent instantaneous readings of their blood sugar levels.

The patient's average blood glucose level over long periods of time, typically several months, is also reflected in the level of HbA1c hemoglobin in the patient's blood. Testing for HbA1c levels is more complex than testing for an instantaneous blood sugar level, and can be done using high performance liquid chromatography (HPLC) in a specialized testing machine. A patient may be tested several times per year and the resulting measured levels of HbA1c used as a check on how well the patient's blood sugar levels are being controlled.

FIG. 1 shows a medical testing machine **100** in accordance with example embodiments of the invention. Example testing machine **100** is configured for testing blood samples for the level of HbA1c hemoglobin, but it will be understood that the principles of the invention are applicable to testing machines used for other purposes or with other technologies as well. Vials **101** containing blood sampled from patients are loaded into racks **102**, which are then placed into testing machine **100** at input location **103**. Vials **101** are examples of containers for patient media, but in other kinds of tests, other kinds of containers may be used. An automated testing system within medical testing machine **100** extracts a quantity from each vial in sequence, and for each sample performs HPLC to determine the level of HbA1c in the blood. When all of the vials in a rack have been tested, the rack is delivered out of the machine at output location **104**. A "STAT input" **105** may be provided for initiating an out-of-sequence test. Placing a vial in STAT input **105** causes the vial to be tested with priority over the vials previously placed at input location **103**.

Test results and other information are shown on a display screen **106**. Display screen **106** may be any suitable type of display, for example a flat panel liquid crystal display (LCD). Display screen **106** may also include a touchscreen, and serve as an input device for receiving inputs from the user of medical testing machine **100**.

HPLC by its nature uses certain consumable materials, for example buffers and washing solution, and packets **107** of consumable materials may be periodically replaced in medical testing machine **100**. The stationary media used in HPLC may also be periodically replaced.

FIG. 2 shows a vial **101** in more detail. Each vial **101** is labeled with a machine-readable label **201** carrying information about the sample. Many different label formats are possible. Example label **201** includes a patient identifier **202**, which may be shown in human-readable form as well as in machine readable form such as in barcode **203**. Label **201** may also include an accession number **204**. An accession number may be a numeric, alphabetic, alphanumeric, symbolic, or other identifier unique to a particular media sample. Accession number **204** may also be encoded into barcode **203**.

[0015] FIG. 3 shows a simplified block diagram of the architecture of medical testing machine **100**, in accordance with embodiments of the invention. A processor **301** generally controls the operation of medical testing machine **100**. Processor **301** may be any suitable kind of microprocessor, microcontroller, digital signal processor, or other circuitry capable of performing the required functions. Memory **302** may include different kinds of memory, alone or in combination, and stores a variety of digital information. For example, memory **302** may include random access memory (RAM), read only memory (ROM), re-writable non-volatile memory such as flash memory, other kinds of memory, or any suitable combination thereof. In particular, memory **302** includes mass storage **303** for non-volatile storage of large quantities of information, for example the results of tests performed by medical testing machine **100**. Mass storage **303** may include magnetic disk storage, optical disk storage, solid state memory, other kinds of storage, or any suitable combination thereof.

[0016] A portion of memory **302** holds instructions that, when executed by processor **301**, cause medical testing machine **100** to perform its intended functions.

[0017] Medical testing machine **100** includes a vial handling mechanism **304**, for moving vials of patient samples through the system for testing. A vial reader **305** reads information from vials **101**. For example, vial reader **305** may be a barcode reader that reads bar coded information such as patient and accession numbers **202** and **204** from a label such as label **201**. In other embodiments, a different mechanism may be provided for obtaining information about a sample, for example a radio frequency identification (RFID) scanner, optical character recognition, or another suitable mechanism. In some embodiments, a user may enter information manually.

[0018] An extraction mechanism **306** automatically, under control of processor **301**, extracts blood from each vial in turn for testing, and delivers the samples to high performance liquid chromatography (HPLC) system **307**. In general, liquid chromatography involves introducing a small quantity of the sampled blood into the flow of a liquid medium, and passing the liquid medium through a stationary medium. Different components of the introduced blood will traverse the stationary medium at different speeds, due to their different interactions with the liquid and stationary media. The stationary medium is sometimes referred to as a "column". After a time, different components of the introduced blood sample will become separated within the column, and the separated components will arrive at the end of the column at different times. A sensor **308** near the end of the column watches for indications that the different components are passing. The indications may be differences in color, refractive index, spectral absorption characteristics, pH, or other characteristics. A brief overview of chromatography is given in co-pending U.S. Patent Application Publication No. 2013/132897 filed November 13, 2012 and titled "Chromatography Configuration Interface".

[0019] The output of sensor **308** passes data to processor **301**, which determines the result of the test. Results may be shown on display screen **106**. Test results are stored in mass storage **303**, in association with other information such as the information read from the vial labels. In particular, a particular test result may be stored in association with the accession number for the tested media, which may later be associated with patient information. Other kinds of information that are preferably included in the test information include the raw sensor output from the test, the time of the most recent calibration of medical testing machine **100** and the resulting calibration parameters, serial numbers or other identifying information about the consumable items used in the test, and any retest rules that were in place at the time of the test. Other kinds of information may also be stored. For example, a particular test may not produce a numerical result, because of a problem with the sample or an irregularity in the particular test. In this situation, the outcome of the test may be that there is no numerical result to report. For the purposes of this disclosure, the term "outcome" encompasses test outcomes with or without numerical results.

[0020] While mass storage **303** is depicted in FIG. 3 as being internal to medical testing machine **100**, other arrangements are possible, and it is intended that the appended claims encompass other arrangements. For example, some or all of mass storage **303** may be external to medical testing machine **100** and connected to medical testing machine **100** by a cable or wireless interface. In some embodiments, mass storage **303** may be in a different location than medical testing machine **100** and connected to medical testing machine **100** through a computer network.

[0021] In order to ensure correct results and proper interpretation of those results, it is important that medical testing machine **100** be calibrated before its first use and periodically thereafter. Calibration typically involves presenting one or more calibration materials having known characteristics to medical testing machine **100**. The calibration material may be actual test media or a synthesized material that mimics actual test media. The calibration material is prepared so as to produce a specific test result, called the assigned value of the calibration material. The calibration material is tested using the testing system, and it will be assumed that the raw output of a test on a particular calibration material corresponds to the assigned value of that calibration material.

[0022] One or more calibration parameters are determined that can be used to adjust the raw output to match the assigned value. The parameters are stored and applied to future tests of patient media samples.

[0023] An example is helpful in explaining the process. FIG. 4A illustrates a package **400** of calibration materials according to an example embodiment. Although other configurations may be used, example package **400** is formed to conveniently be placed into a rack such as one of racks **102** and comprises three vials **401**, **402**, and **403**, which are joined together. Vials **401-403** may be of the shape and size of standard blood collection vials, and are examples of containers that maintain separation between the calibration materials in package **400**. Vial **401** may contain a conditioning

fluid, while vials **402** and **403** contain two different calibration materials. Vial **402** contains a first material having a first assigned value for the HbA1c concentration (31.1 mmol/mol in this example), and vial **403** contains a second material having a second assigned value for the HbA1c concentration (93.4 mmol/mol in this example). Package **400** may be marked in such a way that medical testing machine **100** can automatically recognize it as a package of calibration materials. For example, a first barcode **404** may encode an indication that package **400** is a package of calibration materials, so that when reader **305** encounters barcode **404**, processor **301** immediately recognizes that a calibration sequence is to be run, rather than testing a patient media sample. Other information may be encoded into barcode **404** as well, for example an expiration date of the calibration materials in package **400**, a lot number, or other information.

[0024] Package **400** may be presented to a medical testing machine in any workable manner, for example by placing it in a rack in input location **103** of medical testing machine **100**, or in STAT input **105**.

[0025] In some embodiments, additional barcodes such as barcodes **405** and **406** may provide other information to medical testing machine **100**. For example, barcode **405** may encode the assigned value for the material in vial **402** (31.1 mmol/mol in this example), and barcode **406** may encode the assigned value from the material in vial **403** (93.4 mmol/mol in this example). These values may also be called setpoints, and may be determined at the time the calibration materials are manufactured.

[0026] FIG. 4B illustrates a package **410** of calibration materials. Example package **410** includes vials **411**, **412**, and **413** for holding a conditioning fluid and calibration materials. A label **414** identifies package **410** as a calibration package, and includes a barcode **415** that encodes various information about package **410**. For example, barcode **415** may encode the assigned values of the calibration materials in vials **412** and **413**, an expiration date, a lot number, or other kinds of information. Other calibration configurations are also possible.

[0027] In some embodiments, medical testing machine **100** may present a user interface screen upon recognition that a calibration sequence is to be run. FIG. 5 illustrates an example user interface screen **500** that may be presented on a display such as display **106**. A user of medical testing machine **100** can use user interface screen **500** to instruct medical testing machine to proceed with the calibration sequence, to cancel the calibration, or to take other actions.

[0028] Extraction mechanism **306** may be capable of, under control of processor **301**, performing any mixing or other necessary processing needed in the calibration sequence. For example, extraction mechanism **306** may extract conditioning fluid from vial **401** to prepare the column to run tests. One or more of consumables **107** may be dispensed into either or both of vials **402** and **403**, in order to condition the materials in those vials for the calibration sequence.

[0029] Medical testing machine then extracts samples from vials **402** and **403**, performs its test on them, and stores the results. Because two different materials having different assigned values are tested in this example, this is a two-point calibration. It will be recognized that other embodiments may use a single calibration material, or more than two calibration materials.

[0030] For the purposes of this example, we assume that the test on the material in vial **402** results in a reading of 30.5 mmol/mol, and the test on the material in vial **403** results in a reading of 94.9 mmol/mol. These results are summarized in Table 1 below.

Table 1

Assigned Value	Actual Reading
31.1	30.5
93.4	94.9

Assuming that the discrepancies between the assigned values and the actual readings are due to miscalibration of the medical testing machine, it appears that medical testing machine **100** provides results that are too low for materials with low HbA1c concentrations, and results that are too high for materials with high HbA1c concentrations.

[0031] Medical testing machine **100**, using processor **301**, can ascertain calibration parameters to be applied to future tests to correct the results of future tests. For a two-point calibration, two parameters can be determined based on a linear transformation of the actual readings to the assigned values. It is straightforward to determine for the example readings in Table 1 that

$$\text{Assigned Value} = .9674 * \text{Actual Reading} + 1.5946$$

In this example, the two calibration parameters are the slope (.9674) and intercept (1.5946) of a linear conversion of the actual readings to the assigned values. Assuming that this linear transformation will improve the accuracy of readings at other concentration levels, the slope and intercept are stored and the linear transformation is applied to the results of future tests. For example, if in a future test of media sampled from a patient medical testing machine **100** initially obtains

a reading of 77.4 mmol/mol, that reading would be adjusted before reporting according to

$$\text{Reported result} = .9674 * 77.4 + 1.5946 = 76.5 \text{ mmol/mol.}$$

[0032] The slope and intercept determined in an actual embodiment will depend on the particular testing machine used, the kind of test being performed, and other variables.

[0033] In some embodiments, the internal measurements units used by the testing machine may differ from the units in which test results are presented. For example, in the case of HPLC testing for HbA1c levels, medical testing machine **100** may compute the area of a particular peak in the chromatogram to measure the HbA1c level, but report the test result in mmol/mol. This conversion may be reflected in the calibration.

[0034] Example data for performing a calibration including a unit conversion are shown in Table 2 below. In this example, the unit used internally by the medical testing machine for HbA1c concentration is the area of the chromatogram attributed to the HbA1c peak, in arbitrary units.

Table 2

Assigned Value (mmol/mol)	Actual Reading (arbitrary area units)
31.1	3.282
93.4	7.679

[0035] It is straightforward to determine for the example readings in Table 2 that

$$\text{Assigned Value (mmol/mol)} = 14.169 * \text{Actual Reading (arbitrary units)} - 15.405$$

Thus, a future test that results in an area reading of 7.4 arbitrary units would be reported as

$$\text{Reported result} = 14.169 * 7.4 - 15.405 = 89.4 \text{ mmol/mol.}$$

Other unit conversions may be implemented in this manner.

[0036] In other embodiments, more or fewer calibration points may be used. In a one-point calibration, the single calibration parameter may be a simple scaling factor or offset applied to measured results before reporting. In a three-point calibration, the transformation between the initial and reported readings can be more complex, for example a quadratic formula.

[0037] In the invention, one or more of the calibration materials are stored in a lyophilized form. For example, either or both of the materials in vials **402** and **403** may be in lyophilized form. In this case, the material is reconstituted before testing is done by adding a liquid to the material. The liquid used for reconstitution may be provided in the calibration package, for example in vial **401**, or a liquid already existing in the medical testing machine may be used. For example, in the case of medical testing machine **100** that performs chromatography, the washing solution used in the chromatography may also be used to reconstitute lyophilized calibration materials.

[0038] In reconstituting the lyophilized material, liquid is added to the lyophilized material and the mixture agitated. In the invention, the agitation is accomplished by aspirating some or all of the mixture from the vial being agitated using extraction mechanism **306** and re-injecting the aspirated mixture into the vial. The aspiration and re-injection may be performed as many times as is necessary to ensure thorough mixing.

[0039] In some cases, a medical testing machine according to embodiments may recognize that the calibration failed, and may automatically repeat the calibration. For example, after ascertaining the calibration parameters, processor **301** may compare them with predetermined condition and repeat the calibration if the parameters do not meet the predetermined condition. In the example above, the slope parameter should always be a value greater than zero. If the result of a calibration is that the slope parameter is negative, the calibration is obviously faulty. In this case, the predetermined condition is that the slope parameter must be positive.

[0040] In other embodiments, a calibration may be repeated if a parameter falls outside of an expected range. For example, a calibration may be repeated if the slope differs by more than a predetermined percentage from its expected value, or if the intercept differs by more than a predetermined amount from its expected value. The predetermined amounts will depend on the particular test being performed, the number and kind of calibration parameters, the meas-

urement units used for the actual and expected test results, and other factors. In some embodiments, a test may be repeated if the slope differs from its expected value by more than 1 percent, 2 percent, 5 percent, 10 percent, 25 percent, or another suitable amount. If a repeat calibration still does not produce calibration parameters that are within the expected ranges, the machine may signal that it is in need of maintenance.

[0041] In some embodiments, a medical testing machine provides user feedback about the progress of a calibration. FIG. 6 shows an example user interface screen 600 for this purpose. In example user interface screen 600, an animated counter 601 counts down the time remaining in the calibration sequence. An arrow 602 or shaded feature may rotate around counter 601 to indicate that testing is progressing. For example, arrow 602 may rotate about once per second, or at another suitable speed. Other areas of user interface screen 600 may visually indicate the progress of the calibration. For example, activities may be highlighted in the display. The highlighting may be accomplished by the use of color, animation, or other suitable graphical techniques.

[0042] A testing machine in accordance with the invention stores information about the calibration sequence for later retrieval and examination. The stored information may include the chromatogram obtained for each calibration material, the result measured for each calibration material, the calibration parameters such as a slope and intercept ascertained in the calibration, or other information.

[0043] FIG. 7 illustrates an example user interface screen 700 for recalling stored information relating to a calibration sequence. In user interface screen 700, a user may highlight the test of a particular calibration material, for example by touching screen 106. In FIG. 7, a particular calibrator result 701 has been highlighted. Another control 702 may allow selection of particular calibrator results associated with the calibration. In example screen, both tabular data 703 and the chromatogram 704 for the highlighted calibrator sample are displayed. The calibration parameters are also displayed 705.

[0044] While embodiments of the invention have been described above in the context of a machine that tests blood for levels of HbA1c hemoglobin using HPLC, it is to be understood that the principles of the invention may be embodied in other kinds of testing machines that perform different tests on other fluids, tissue, or other patient media.

Claims

1. A method of performing a calibration in a medical testing machine comprising an extraction mechanism for aspirating and re-injecting liquids, the method comprising:

automatically detecting that a package of calibration material has been inserted into the medical testing machine; performing, by the medical testing machine, a calibration sequence using the calibration material to ascertain a calibration parameter for the medical testing machine; and

storing the calibration parameter in electronic storage for use in later tests performed by the medical testing machine;

the method being **characterized in that** the package of calibration material comprises a vial in which the calibration material is provided in a lyophilized state, and the method further comprises controlling the medical testing machine to automatically reconstitute the lyophilized material before performing the calibration sequence by using the extraction mechanism to add a liquid to the vial containing the material in the lyophilized state; and wherein the method further comprises using the extraction mechanism for agitating the reconstituted material by aspirating at least some of the reconstituted material from the vial containing the reconstituted material and by re-injecting the aspirated reconstituted material into the vial.

2. The method of claim 1, further comprising reading a calibration setpoint from the package of calibration material.

3. The method of claim 1, wherein the medical testing machine performs liquid chromatography that uses a washing solution, and wherein the washing solution is also used to reconstitute the lyophilized material.

4. The method of claim 1, wherein the medical testing machine performs high performance liquid chromatography.

5. The method of claim 1, wherein the medical testing machine performs a test that measures a level of HbA1c hemoglobin in blood.

6. The method of claim 1, further comprising:

comparing the calibration parameter with a predetermined condition; and
automatically re-running the calibration if the calibration parameter does not meet the predetermined condition.

7. The method of claim 1, further comprising:

comparing the calibration parameter with a predetermined condition; and
automatically re-running the calibration if the calibration parameter meets the predetermined condition.

8. The method of claim 1, wherein the calibration is a two-point calibration, and wherein two calibration parameters are ascertained,
preferably the calibration parameters include a slope and an intercept.

9. A medical testing machine, comprising:

a testing system for performing a medical test on media sampled from patients;
an extraction mechanism for aspirating and re-injecting liquids;
a media handling mechanism;
a processor; and
a memory, the memory holding instructions that when executed by the processor cause the medical testing machine to:

automatically recognize that a package of calibration material has been inserted into the medical testing machine, wherein the package of calibration material comprises a vial in which at least some of the calibration material is in a lyophilized state;
perform, a calibration sequence using the calibration material to ascertain a calibration parameter for the medical testing machine; and
store the calibration parameter in the memory for use in later tests performed by the medical testing machine;
the medical testing machine being **characterized in that** the instructions, when executed by the processor, further cause the extraction mechanism of the medical testing machine to, as part of the calibration sequence, add a liquid to the vial containing the material in the lyophilized state in order to automatically reconstitute at least some of the calibration material from the lyophilized state;
and wherein the instructions, when executed by the processor, further cause the extraction mechanism of the medical testing machine to agitate the reconstituted material by aspirating at least some of the reconstituted material from the vial containing the reconstituted material and reinjecting the aspirated reconstituted material into the vial.

10. The medical testing machine of claim 9, wherein the medical testing machine further comprises a STAT input, wherein the medical testing machine automatically recognizes that the package of calibration material has been inserted into the STAT input.

11. The medical testing machine of claim 9, wherein the medical testing machine performs high performance liquid chromatography.

12. The medical testing machine of claim 9, wherein the medical testing machine performs a test that measures a level of HbA1c hemoglobin in blood.

13. The medical testing machine of claim 9, wherein the medical testing machine further comprises a display, and wherein the instructions, when executed by the processor, further cause the medical testing machine to present a user interface screen on the display indicating the progress of the calibration sequence, preferably the display is a touchscreen display.

Patentansprüche

1. Verfahren zur Durchführung einer Eichung bei einer medizinischen Testmaschine, die einen Extraktionsmechanismus zum Absaugen und Rückinjizieren von Flüssigkeiten umfasst, wobei das Verfahren umfasst:

automatisches Nachweisen, dass ein Eichmaterialpaket in die medizinische Testmaschine eingefügt wurde;
Durchführung einer Eichsequenz mit der medizinischen Testmaschine, wobei das Eichmaterial verwendet wird, um einen Eichparameter für die medizinische Testmaschine zu ermitteln; und
Speichern des Eichparameters in einem elektronischen Speicher zur Verwendung in späteren Tests, die von

der medizinischen Testmaschine durchgeführt werden;

wobei das Verfahren **dadurch gekennzeichnet ist, dass** das Eichmaterialpaket eine Stechampulle umfasst, in der das Eichmaterial in einem lyophilisierten Zustand bereitgestellt wird, und das Verfahren weiterhin das Steuern der medizinischen Testmaschine in einer solchen Weise umfasst, dass das lyophilisierte Material automatisch rekonstituiert wird, bevor die Eichungssequenz durchgeführt wird, wobei der Extraktionsmechanismus verwendet wird, um eine Flüssigkeit in die Stechampulle, die das Material im lyophilisierten Zustand enthält, zu geben;

und wobei das Verfahren weiterhin das Verwenden des Extraktionsmechanismus umfasst, um das rekonstituierte Material dadurch zu durchmischen, dass wenigstens ein Teil des rekonstituierten Materials aus der Stechampulle, die das rekonstituierte Material enthält, abgesaugt wird und das abgesaugte rekonstituierte Material in die Stechampulle zurück injiziert wird.

2. Verfahren gemäß Anspruch 1, weiterhin umfassend das Ablesen eines Eichsollwerts aus dem Eichmaterialpaket.

3. Verfahren gemäß Anspruch 1, wobei die medizinische Testmaschine Flüssigchromatographie durchführt, bei der eine Waschlösung verwendet wird, und wobei die Waschlösung auch verwendet wird, um das lyophilisierte Material zu rekonstituieren.

4. Verfahren gemäß Anspruch 1, wobei die medizinische Testmaschine HPLC (Hochleistungsflüssigchromatographie) durchführt.

5. Verfahren gemäß Anspruch 1, wobei die medizinische Testmaschine einen Test durchführt, der die Konzentration von HbA1c-Hämoglobin im Blut misst.

6. Verfahren gemäß Anspruch 1, weiterhin umfassend:

Vergleichen des Eichparameters mit einem vorbestimmten Zustand; und
automatisches Wiederholen der Eichung, wenn der Eichparameter den vorbestimmten Zustand nicht erfüllt.

7. Verfahren gemäß Anspruch 1, weiterhin umfassend:

Vergleichen des Eichparameters mit einem vorbestimmten Zustand; und
automatisches Wiederholen der Eichung, wenn der Eichparameter den vorbestimmten Zustand erfüllt.

8. Verfahren gemäß Anspruch 1, wobei die Eichung eine Zweipunkteichung ist und wobei die zwei Eichparameter ermittelt werden, wobei die Eichparameter vorzugsweise eine Steigung und einen Achsenabschnitt umfassen.

9. Medizinische Testmaschine, umfassend:

ein Testsystem zum Durchführen eines medizinischen Tests an Medien, die als Proben von Patienten genommen wurden;

einen Extraktionsmechanismus zum Absaugen und Rückinjizieren von Flüssigkeiten;

einen Medienhandhabungsmechanismus;

einen Prozessor; und

einen Speicher, wobei der Speicher Anweisungen enthält, die bei Ausführung durch den Prozessor bewirken, dass die medizinische Testmaschine:

automatisch erkennt, dass ein Eichmaterialpaket in die medizinische Testmaschine eingefügt wurde, wobei das Eichmaterialpaket eine Stechampulle umfasst, in der wenigstens ein Teil des Eichmaterials in einem lyophilisierten Zustand vorliegt;

eine Eichsequenz durchführt, wobei das Eichmaterial verwendet wird, um einen Eichparameter für die medizinische Testmaschine zu ermitteln; und

den Eichparameter zur Verwendung in späteren Tests, die von der medizinischen Testmaschine durchgeführt werden, in dem Speicher speichert;

wobei die medizinische Testmaschine **dadurch gekennzeichnet ist, dass** die Anweisungen bei Ausführung durch den Prozessor weiterhin bewirken, dass der Extraktionsmechanismus der medizinischen Testmaschine als Teil der Eichsequenz eine Flüssigkeit in die Stechampulle, die das Material in dem lyophili-

sierten Zustand enthält, gibt, um wenigstens einen Teil des Eichmaterials aus dem lyophilisierten Zustand automatisch zu rekonstituieren;

und wobei die Anweisungen bei Ausführung durch den Prozessor weiterhin bewirken, dass der Extraktionsmechanismus der medizinischen Testmaschine das rekonstituierte Material dadurch durchmischt, dass wenigstens ein Teil des rekonstituierten Materials aus der Stechampulle, die das rekonstituierte Material enthält, abgesaugt wird und das abgesaugte rekonstituierte Material in die Stechampulle zurück injiziert wird.

10. Medizinische Testmaschine gemäß Anspruch 9, wobei die medizinische Testmaschine weiterhin einen STAT-Input umfasst, wobei die medizinische Testmaschine automatisch erkennt, dass das Eichmaterialpaket in den STAT-Input eingefügt wurde.

11. Medizinische Testmaschine gemäß Anspruch 9, wobei die medizinische Testmaschine HPLC (Hochleistungsflüssigchromatographie) durchführt.

12. Medizinische Testmaschine gemäß Anspruch 9, wobei die medizinische Testmaschine einen Test durchführt, der die Konzentration von HbA1c-Hämoglobin im Blut misst.

13. Medizinische Testmaschine gemäß Anspruch 9, wobei die medizinische Testmaschine weiterhin eine Anzeige umfasst und wobei die Anweisungen bei Ausführung durch den Prozessor weiterhin bewirken, dass die medizinische Testmaschine auf der Anzeige einen Benutzeroberflächenbildschirm präsentiert, der den Fortschritt der Eichsequenz anzeigt, wobei die Anzeige vorzugsweise eine Touchscreen-Anzeige ist.

Revendications

1. Procédé pour effectuer un étalonnage dans une machine d'analyse médicale comprenant un mécanisme d'extraction destiné à aspirer et réinjecter des liquides, le procédé comprenant les étapes consistant à :

détecter automatiquement qu'un lot de matériau d'étalonnage a été inséré dans la machine d'analyse médicale ; exécuter, par l'intermédiaire de la machine d'analyse médicale, une séquence d'étalonnage en utilisant le matériau d'étalonnage pour déterminer un paramètre d'étalonnage pour la machine d'analyse médicale ; et stocker le paramètre d'étalonnage dans une mémoire électronique pour l'utiliser dans des analyses ultérieures effectuées par la machine d'analyse médicale ;

le procédé étant **caractérisé en ce que** le lot de matériau d'étalonnage comprend un flacon dans lequel le matériau d'étalonnage est fourni dans un état lyophilisé, et le procédé comprenant en outre la commande de la machine d'analyse médicale pour reconstituer automatiquement le matériau lyophilisé avant d'effectuer la séquence d'étalonnage en utilisant le mécanisme d'extraction pour ajouter un liquide au flacon contenant le matériau à l'état lyophilisé ;

et dans lequel le procédé comprend en outre l'utilisation du mécanisme d'extraction pour agiter le matériau reconstitué en aspirant au moins une partie du matériau reconstitué depuis le flacon contenant le matériau reconstitué et en réinjectant le matériau reconstitué aspiré dans le flacon.

2. Procédé selon la revendication 1, comprenant en outre la lecture d'un point de consigne d'étalonnage à partir du lot de matériau d'étalonnage.

3. Procédé selon la revendication 1, dans lequel la machine d'analyse médicale effectue une chromatographie en phase liquide qui utilise une solution de lavage, et dans lequel la solution de lavage est également utilisée pour reconstituer le matériau lyophilisé.

4. Procédé selon la revendication 1, dans lequel la machine d'analyse médicale effectue une chromatographie en phase liquide à haute performance.

5. Procédé selon la revendication 1, dans lequel la machine d'analyse médicale effectue une analyse qui mesure un niveau d'hémoglobine HbA1c dans le sang.

6. Procédé selon la revendication 1, comprenant en outre les étapes consistant à :

comparer le paramètre d'étalonnage à une condition prédéterminée ; et

relancer automatiquement l'étalonnage si le paramètre d'étalonnage ne répond pas à la condition prédéterminée.

7. Procédé selon la revendication 1, comprenant en outre les étapes consistant à :

5 comparer le paramètre d'étalonnage à une condition prédéterminée ; et
relancer automatiquement l'étalonnage si le paramètre d'étalonnage répond à la condition prédéterminée.

8. Procédé selon la revendication 1, dans lequel l'étalonnage est un étalonnage à deux points, et dans lequel deux
10 paramètres d'étalonnage sont déterminés,
les paramètres d'étalonnage comprenant de préférence une pente et une intersection.

9. Machine d'analyse médicale comprenant :

15 un système d'analyse destiné à effectuer une analyse médicale sur des milieux prélevés sur des patients ;
un mécanisme d'extraction destiné à aspirer et à réinjecter des liquides ;
un mécanisme de manipulation de milieux ;
un processeur ; et
une mémoire, la mémoire contenant des instructions qui, lorsqu'elles sont exécutées par le processeur, amènent
la machine d'analyse médicale à :

20 reconnaître automatiquement qu'un lot de matériau d'étalonnage a été inséré dans la machine d'analyse
médicale, le lot de matériau d'étalonnage comprenant un flacon dans lequel au moins une partie du matériau
d'étalonnage est dans un état lyophilisé ;
effectuer une séquence d'étalonnage en utilisant le matériau d'étalonnage afin de déterminer un paramètre
25 d'étalonnage pour la machine d'analyse médicale ; et
stocker le paramètre d'étalonnage dans la mémoire pour l'utiliser dans des analyses ultérieures effectuées
par la machine d'analyse médicale ;
la machine d'analyse médicale étant **caractérisé en ce que** les instructions, lorsqu'elles sont exécutées
par le processeur, amènent en outre le mécanisme d'extraction de la machine d'analyse médicale à ajouter,
30 dans le cadre de la séquence d'étalonnage, un liquide dans le flacon contenant le matériau à l'état lyophilisé
afin de reconstituer automatiquement au moins une partie du matériau d'étalonnage à partir de l'état
lyophilisé ;
et où les instructions, lorsqu'elles sont exécutées par le processeur, amènent en outre le mécanisme
d'extraction de la machine d'analyse médicale à agiter le matériau reconstitué en aspirant au moins une
35 partie du matériau reconstitué depuis le flacon contenant le matériau reconstitué et en réinjectant le matériau
reconstitué aspiré dans le récipient.

10. Machine d'analyse médicale selon la revendication 9, dans laquelle la machine d'analyse médicale comprend en
40 outre une entrée STAT, dans laquelle la machine d'analyse médicale reconnaît automatiquement que le lot de
matériau d'étalonnage a été inséré dans l'entrée STAT.

11. Machine d'analyse médicale selon la revendication 9, dans laquelle la machine d'analyse médicale effectue une
chromatographie en phase liquide à haute performance.

45 12. Machine d'analyse médicale selon la revendication 9, dans laquelle la machine d'analyse médicale effectue une
analyse qui mesure un niveau d'hémoglobine HbA1c dans le sang.

13. Machine d'analyse médicale selon la revendication 9, dans laquelle la machine d'analyse médicale comprend en
50 outre un affichage, et dans laquelle les instructions, lorsqu'elles sont exécutées par le processeur, amènent en outre
la machine d'analyse médicale à présenter sur l'affichage un écran d'interface utilisateur qui signale l'avancement
de la séquence d'étalonnage, l'affichage étant de préférence un écran tactile.

55

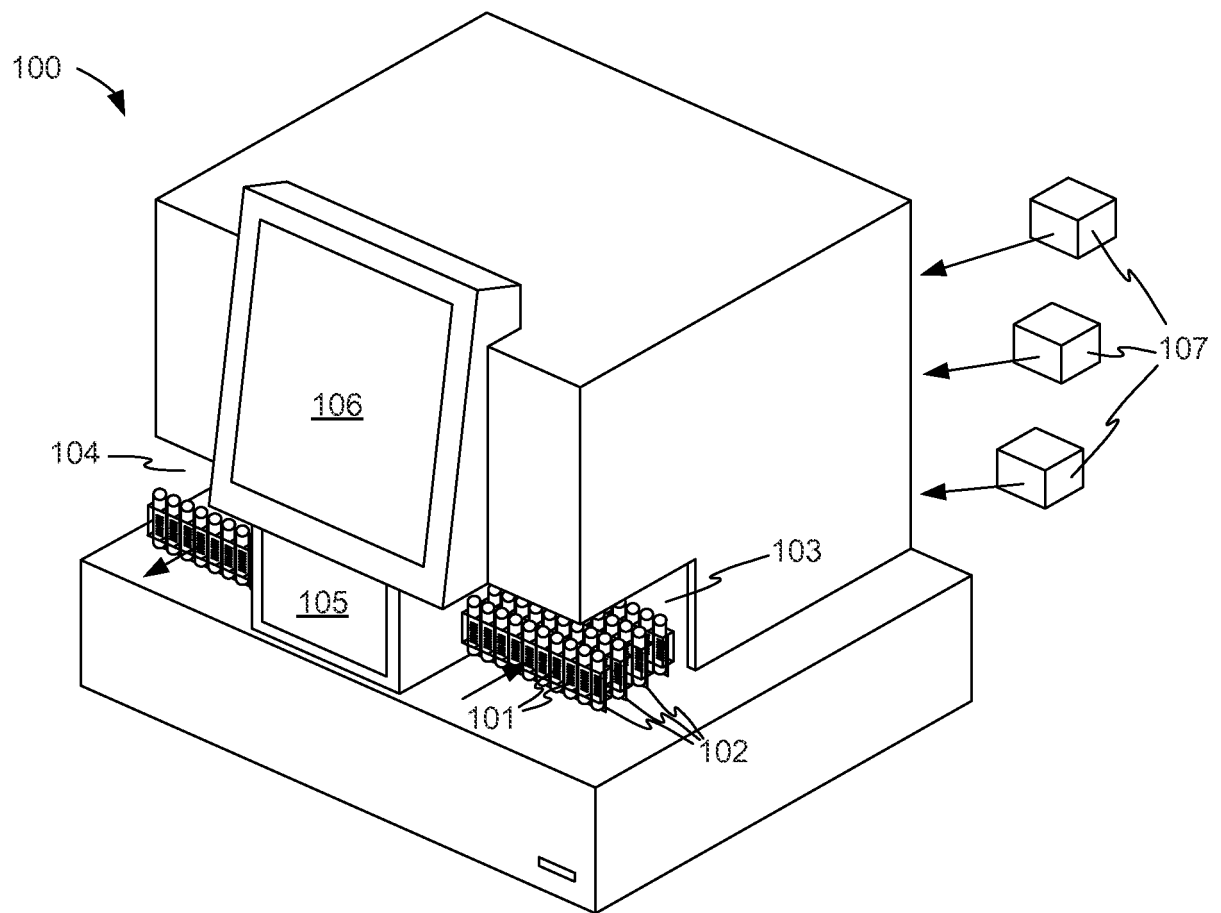


FIG. 1

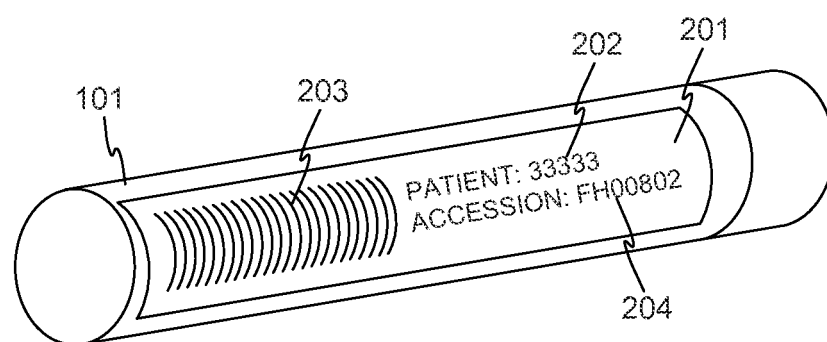


FIG. 2

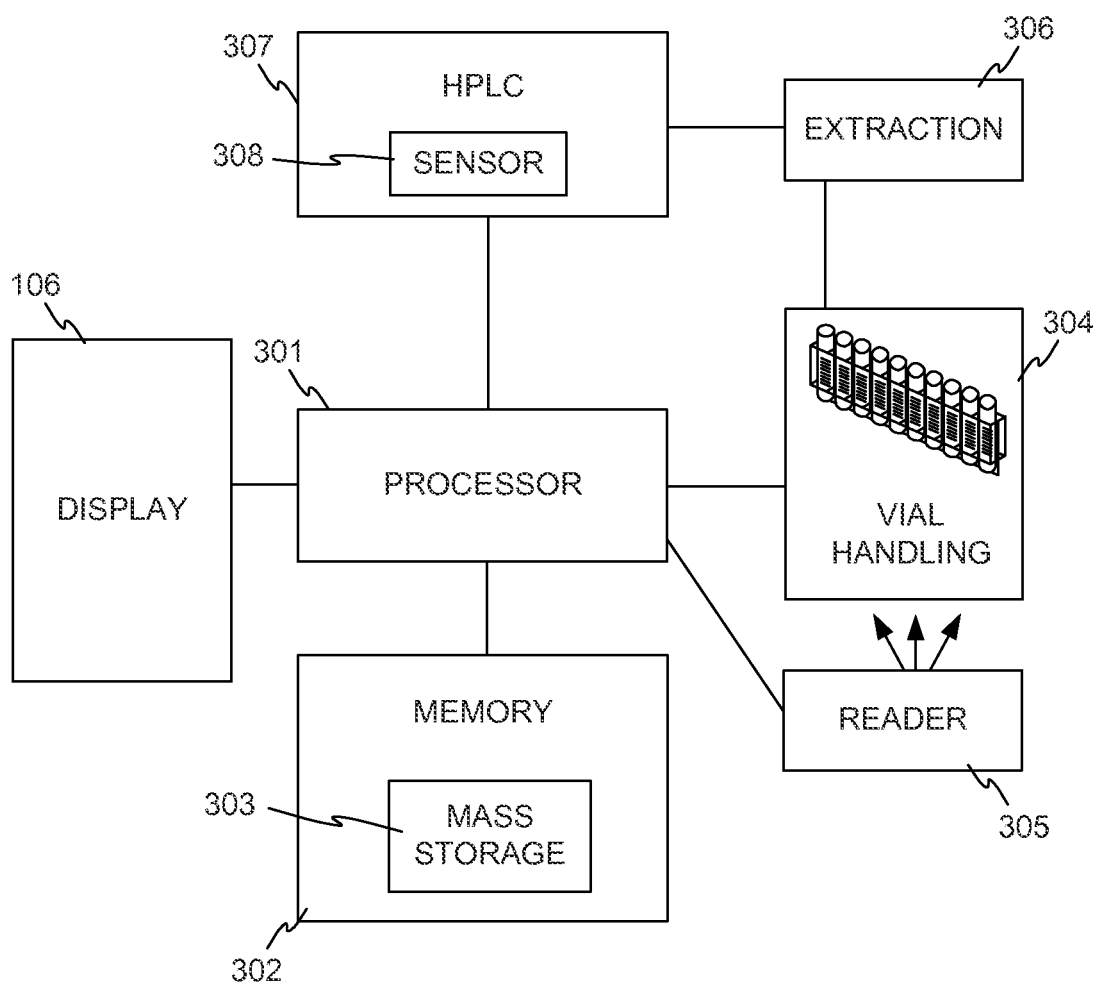


FIG. 3

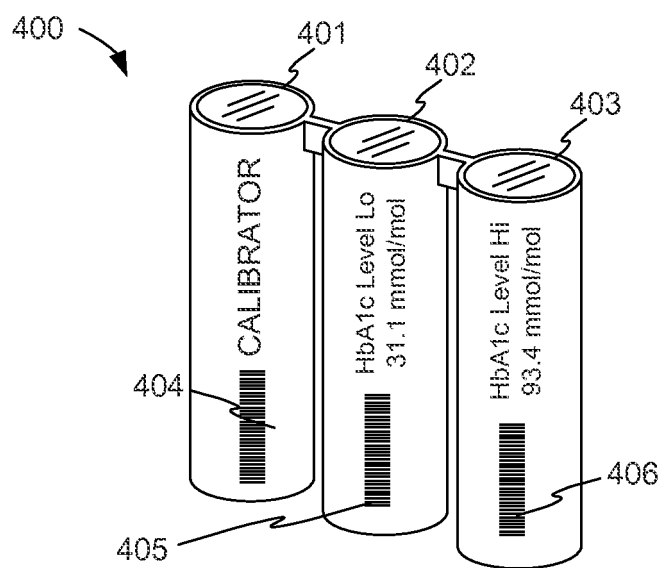


FIG. 4A

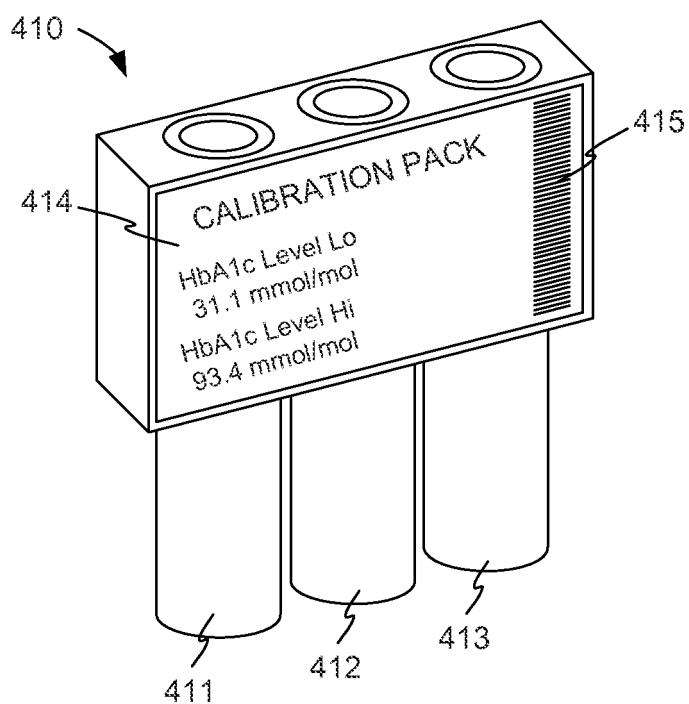


FIG. 4B

500

Assay: HbA1c ▼

Lot Number: AA82114

Expiration: 1/31/2013 ▼

Component:	Assigned Value	Stat Position
Conditioner	N/A	1
Level 1	31.1 mmol/mol	2
Level 2	93.4 mmol/mol	3

☐ Calibrate without reconstituting
(or calibrate with prediluted material)

Open Stat Drawer

Calibrate Now

Cancel

FIG. 5

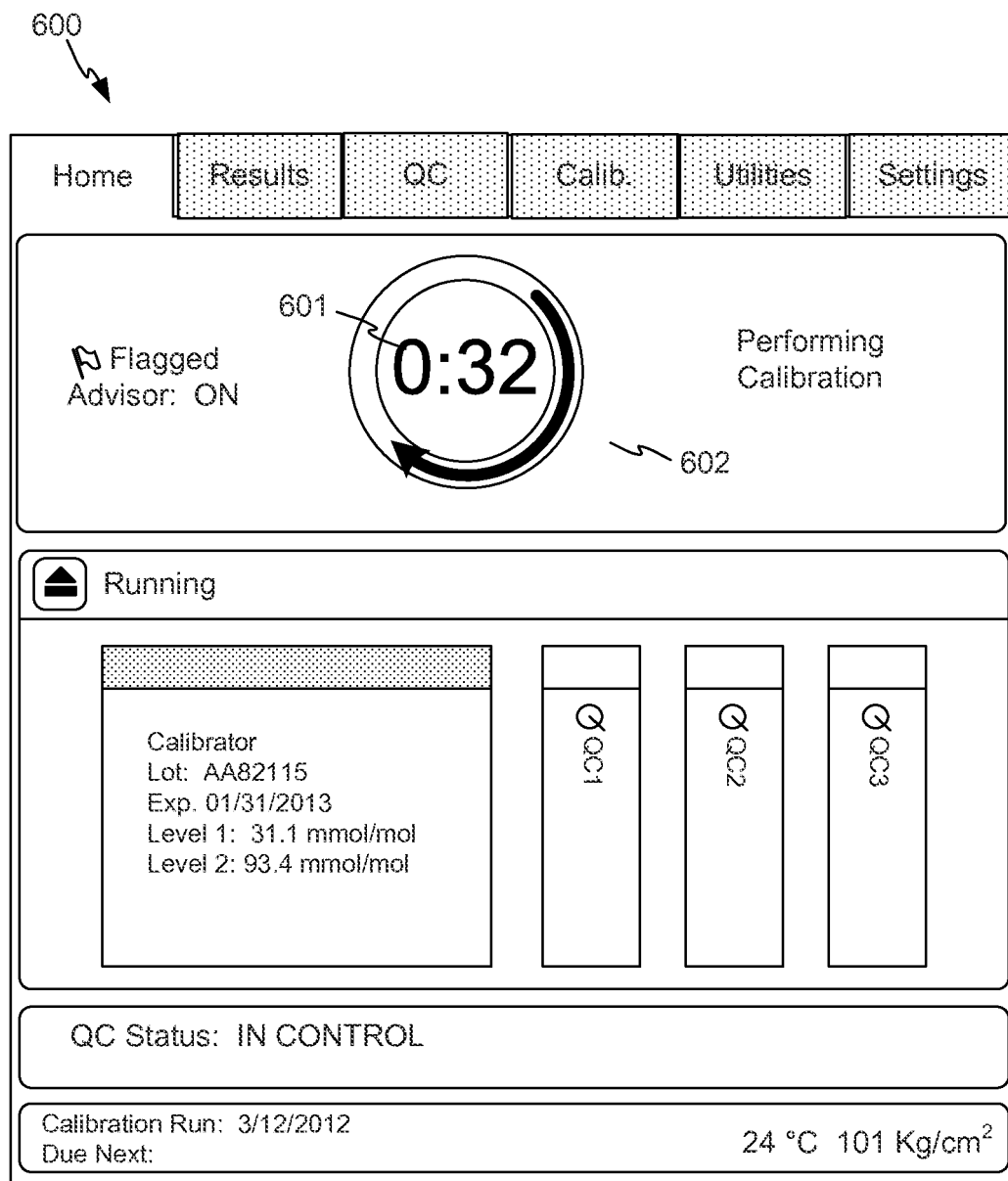


FIG. 6

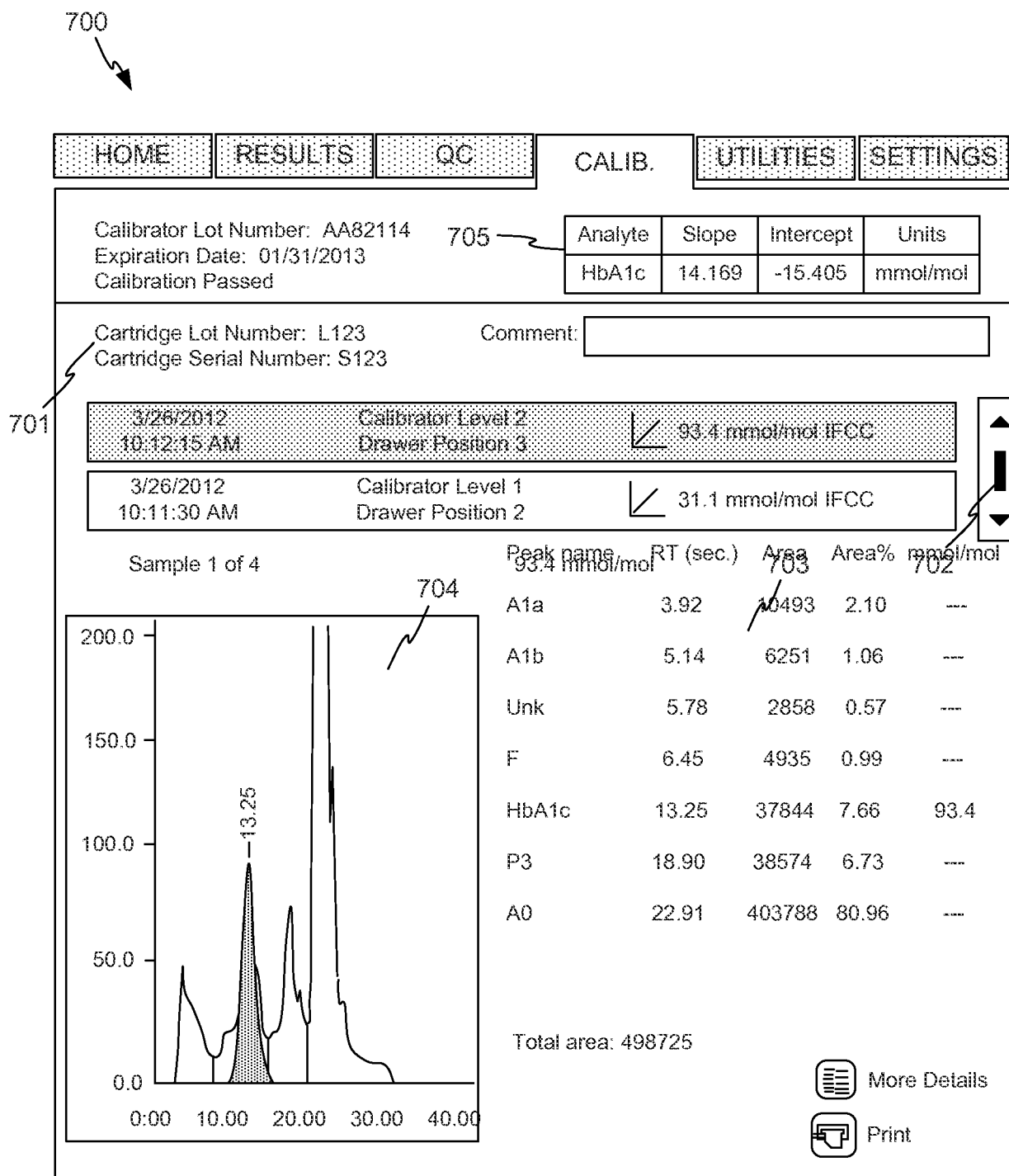


FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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